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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,965	08/04/2003	Paul Alfred Cimiluca	9152R	5180

27752 7590 03/09/2004

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EXAMINER

WHITE, EVERETT NMN

ART UNIT PAPER NUMBER

1623

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,965

Applicant(s)

CIMILUCA ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date November 17, 2003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-23 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-40 of copending Application No. 10/368,514. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. Claims 24-43 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-56 of copending Application No. 10/369,039. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al (US Patent No. 6,045,847) in view of Marlett et al (US Patent No. 6,287,609) or Colliopoulos (US Patent No. 5,009,916).

Applicants claim a composition comprising: (a) a polysaccharide component comprising xylose and arabinose, wherein the ratio of xylose to arabinose is at least about 3:1, by weight; wherein the composition further comprises: (i) optionally, a first surrounding layer which surrounds the agglomerates, wherein the first surrounding layer is a hydrophobic layer; and (ii) optionally, a second surrounding layer which surrounds the agglomerates, wherein the second surrounding layer is a hydrophilic layer; wherein the composition comprises at least one of the first surrounding layer and the second surrounding layer, and wherein when the composition comprises the first surrounding layer and the second surrounding layer then the first surrounding layer is a preceding layer relative to the second surrounding layer. Applicants also claim a composition comprising a plurality of polysaccharide particles, wherein the polysaccharide particles comprises a polysaccharide component comprising the xylose and arabinose. Additional limitations in the dependent claims include specific amount of agglomerates in the composition; specific water vapor transmission rate of the first surrounding layer;

specific components of the first and second surrounding layers; specific coating weight of the first surround layer; specific mean particle size of the agglomerates; further polysaccharide components of the composition; the agglomerates having a specific dispersing component; the agglomerates comprising a specific edible acid; the composition further comprising a starch or gum.

The Nakamura et al patent shows that compositions that comprise xylose and arabinose are well known in the art. Nakamura et al discloses a water-soluble hemicellulose, which is a polysaccharide containing xylose and arabinose along with other constituent saccharides that include galactose, fucose, rhamnose and galacturonic acid. Nakamura et al discloses that the water-soluble hemicellulose can be used as a dietary fiber additive for foods, which includes rice. Nakamura et al discloses that the water-soluble hemicellulose may be used alone or in an emulsified state with fat or oil to achieve the function of producing a shorter soaking time and allowing a greater amount of water to permeate the rice, but also sets forth that other quality enhancers or additives may be combined therewith as deemed suitable. Examples of quality enhancers and additives listed in the Nakamura et al patent include guar gum, process starch and other starches. Nakamura et al also teaches that the water-soluble hemicellulose as part of a soaking time-shortening agent for grain preparation may be distributed and sold in emulsified or suspended form with a fat or oil, or in solution form in water, saline or a solution of an organic acid such as acetic acid. The water-soluble hemicellulose composition of the Nakamura et al patent comprising the named constituent saccharides and quality enhancers or additives such as guar gum, starch and acetic acid embraces the instantly claimed composition comprising the named polysaccharide components and binders, suspending agents and edible acids thereof. The composition of the instant claims differ from the composition of the Nakamura et al patent by claiming the xylose and arabinose of the polysaccharide component as having a ratio at least about 3:1, by weight. The Marlett et al patent discloses psyllium seed husks that can be used as a dietary substance to promote laxation and also as a hypocholesterolemic agent (see abstract). Marlett et al teaches the preparation of fractions obtained from psyllium seed husks that comprised mostly of xylose and

arabinose. See column 4, lines 48-53 of the Marlett et al patent wherein a fraction B obtained from psyllium seed husks has 50% xylose and arabinose by weight and in a preferred embodiment at least 85% xylose and arabinose by weight. Also see column 5, lines 3-6 wherein Marlett et al discloses the ratio of weights of xylose to arabinose of Fraction B as being between 2.5 and 4.5, and between 3.0 and 4.0 in a preferred embodiment, which covers the xylose to arabinose ratio set forth in the instant claims.

The composition of the instant claims also differ from the composition of the Nakamura et al patent by claiming that the composition comprises a plurality of agglomerates comprising a polysaccharide component comprising xylose and arabinose. The Colliopoulos patent shows that a psyllium high fiber drink mix made by agglomerating a base comprising at least 5 to 99 weight percent psyllium muciloid is well known in the art (see column 2, lines 33-39). See column 3, 5th full paragraph of the Colliopoulos patent, wherein the high fiber drink composition may be manufactured by coating the dry blended ingredients with a selection of materials that include gums and cellulose derivatives, which is encompassed by the first and second surrounding layers set forth in instant Claims 7 and 8. Also, see column 1, 3rd paragraph of the Colliopoulos patent, which set forth that psyllium muciloid is useful in the treatment of constipation, which encompasses the subject matter of instant Claims 22, 23 and 43. The Marlett et al patent, discussed above, establishes that psyllium comprises xylose and arabinose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polysaccharide comprising xylose and arabinose used in the dietary composition of the Nakamura et al patent with a psyllium seed husk fraction comprising xylose and arabinose at a specific ratio and to agglomerate these ingredients in view of the recognition in the art, as evidenced by the Marlett et al and Colliopoulos patents, that use of a dietary composition comprising psyllium as a component is effective as a laxative and hypocholesterolemic agent.

One of ordinary skill in this art would be motivated to combine the teachings of the Nakamura et al, Marlett et al and Colliopoulos patents in a rejection of the claims

under 35 U.S.C. 103 since all the patents set forth dietary compositions that comprise xylose and arabinose.

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al and Marlett et al as applied to Claims 1-43 above, and further in view of Barbera (US Patent No. 5,425,945).

Applicants claim a composition comprising plurality of polysaccharide particles, wherein the polysaccharide particles comprise polysaccharide component comprising xylose and arabinose, wherein the ratio of xylose to arabinose is at least about 3:1, by weight, and wherein the polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns, wherein the polysaccharide particles each independently, comprise: (i) optionally, a first surrounding layer which surrounds the agglomerates, wherein the first surrounding layer is a hydrophobic layer; and (ii) optionally, a second surrounding layer which surrounds the agglomerates, wherein the second surrounding layer is a hydrophilic layer; wherein the composition comprises at least one of the first surrounding layer and the second surrounding layer, and wherein when the composition comprises the first surrounding layer and the second surrounding layer then the first surrounding layer is a preceding layer relative to the second surrounding layer.

The information set forth for the Nakamura et al and Marlett et al patents in the above rejection is incorporated into the current rejection. The instant claims differ from the Nakamura et al and Marlett et al patents by claiming polysaccharide particles having a mean particle size distribution of from about 0.001 microns to about 150 microns. In Example 1, the Barbera patent shows polysaccharide particles having the instantly claimed particle size is well known in the art. Example 1 discloses a psyllium-containing dry blend having a particle size of 100 mesh screen (e.g., 150 microns). The Marlett et al patent establishes that psyllium husk contains xylose and arabinose components in a xylose to arabinose ratio at least 3:1, by weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polysaccharide composition comprising xylose and

arabinose used in the dietary composition establish by the combination of the Nakamura et al patent and the Marlett et al patent with a psyllium-containing composition in view of the recognition in the art, as evidenced by the Barbera patent, that the psyllium material as part of the composition improves the mixability and dispersibility of the composition in liquids.

One of ordinary skill in this art would be motivated to combine the teachings of the Nakamura et al and Marlett et al patents with the teachings of the Barbera patent in a rejection of the claims under 35 U.S.C. 103 since all the patents set forth dietary compositions that comprise xylose and arabinose components.

Summary

7. All the Claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

8. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


E. White

James O. Wilson
Supervisory Primary Examiner
Technology Center 1600